

01/24/02
01/26/01-~~PRV~~

10/056420

What is claimed is:

1. A method of treating an HIV-infected
individual, comprising:

112P1
5 (a) treating an HIV-infected individual with at
least one anti-retroviral compound;

(b) immunizing said individual with an HIV
immunogenic composition;

VACCINE

(c) withdrawing treatment with said anti-
retroviral compound;

10 (d) reinitiating treatment with at least one
anti-retroviral compound;

(e) repeating step (c) at least once; and

(f) optionally repeating step (d) at least once.

20 2. The method of claim 1, wherein said
15 immunization induces an anti-HIV CD4+ T helper cell
response.

3. The method of claim 1, wherein said
immunization comprises administering said HIV immunogenic
composition more than once.

20 4. The method of claim 1, wherein said HIV
immunogenic composition comprises a whole-killed HIV virus
devoid of outer envelope protein gp120.

5. The method of claim 1, wherein said HIV
immunogenic composition comprises an adjuvant.

25 6. The method of claim 5, wherein said adjuvant
comprises incomplete Freund's adjuvant

10056420-012402

7. The method of claim 1, wherein said HIV immunogenic composition comprises at least one immunostimulatory sequence (ISS).

8. The method of claim 1, wherein said HIV
5 immunogenic composition is REMUNE™.

9. The method of claim 1, wherein said HIV immunogenic composition is a combination of REMUNE™ and at least one ISS.

10. The method of claim 1, wherein said anti-
10 retroviral compound is selected from the group consisting of a protease inhibitor, a reverse transcriptase inhibitor and a ribonucleotide reductase inhibitor.

11. The method of claim 1, wherein said anti-
retroviral compound is selected from the group consisting
15 of a viral adsorption inhibitor, an HIV entry inhibitor, an integrase inhibitor and a virus-cell fusion inhibitor.

12. The method of claim 1, wherein said anti-
retroviral treatment in step (a) reduces HIV viral load to less than 5000 copies/ml.

20 13. The method of claim 1, wherein said anti-
retroviral treatment in step (a) reduces HIV viral load to less than 500 copies/ml.

14. The method of claim 1, wherein said anti-
retroviral treatment in step (a) reduces HIV viral load to
25 less than 50 copies/ml.

10056420 012402

15. The method of claim 1, wherein said withdrawal in step (c) is for a period of time until viral load rises to greater than about 100,000 copies/ml.

16. The method of claim 1, wherein said withdrawal in step (c) is for a period of time until viral load rises to greater than about 50,000 copies/ml.

17. The method of claim 1, wherein said withdrawal in step (c) is for a period of time until viral load rises to greater than about 20,000 copies/ml.

18. The method of claim 1, wherein said withdrawal in step (c) is for a period of at least 2 weeks.

19. The method of claim 1, wherein said withdrawal in step (c) is for a period of about 8 weeks.

20. The method of claim 1, wherein reinitiating said anti-retroviral treatment in step (d) reduces HIV viral load to less than 5000 copies/ml.

21. The method of claim 1, wherein reinitiating said anti-retroviral treatment in step (d) reduces HIV viral load to less than 500 copies/ml.

22. The method of claim 1, wherein reinitiating said anti-retroviral treatment in step (d) reduces HIV viral load to less than 50 copies/ml.

23. The method of claim 1, wherein said reinitiated anti-retroviral treatment in step (d) is for a period of about 8 weeks.

2042420"012402

24. The method of claim 1, wherein HIV viral load in said individual following step (e) is maintained at less than about 10,000 copies/ml for a period of at least about 8 weeks.

5 25. The method of claim 1, wherein HIV viral load in said individual following step (e) is maintained at less than about 5,000 copies/ml for a period of at least about 8 weeks.

10 26. The method of claim 1, wherein HIV viral load in said individual following step (e) is maintained at less than about 500 copies/ml for a period of at least about 8 weeks.

204210 02495001